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10/577,679	04/28/2006	Britta Hardy	31831	9819

  

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EXAMINER	
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1654	

  

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/577,679

Applicant(s)

HARDY ET AL.

Examiner

Ronald T. Niebauer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-38, 44, 46, 53, 56, 58, 60, 62 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-38, 44, 46, 53, 56, 58, 60, 62, 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicants amendments and arguments filed 11/13/07 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 1-35,39-43,45,47-52,54-55,57,59,61,63-69 have been cancelled. Claim 70 has been added as a new claim.

Claims 36-38,44,46,53,56,58,60,62,70 are under consideration.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 36-38,44,46,53,56,58,60,62** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 uses the closed language of 'consisting of' in reference to the peptide sequences (SEQ ID NO: 6 and 10). Section 2111.03 of the MPEP states that the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. However, dependent claim 60 recites that the peptide is a cyclic peptide. A cyclic peptide of claim 60 would require an additional element as compared to the peptide of claim 37. It is noted that the sequences (SEQ ID NO:6 and 10) do not recite or give any indication that the peptides are cyclic (for example, via a disulfide bond between cysteine residues). As such, the scope of claim 37 and

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dependent claims 53,56,60 is unclear since the claims appear to be drawn to both open and closed language.

Claim 36 uses the open language 'comprising' followed by the closed language 'consisting' followed by a statement that broadens (up to 50 amino acids in length) from consisting of SEQ ID NO: 6 and 10 (SEQ ID NO:6 and 10 are each 12 amino acids in length). Section 2111.03 of the MPEP states that the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. A peptide consisting of SEQ ID NO:6 or 10 can only be 12 amino acids in length. However, claim 36 is drawn to peptides up to 50 amino acids in length. Further, dependent claim 38 states that the peptide is cyclic. A cyclic peptide of claim 38 would require an additional element as compared to the peptide consisting of SEQ ID NO:6 or 10 as recited in claim 36. It is noted that the sequences (SEQ ID NO:6 and 10) do not recite or give any indication that the peptides are cyclic (for example, via a disulfide bond between cysteine residues). As such, the scope of claim 36 and dependent claim 38 is unclear since the claims appear to be drawn to both open and closed language.

Claim 46 uses the open language 'comprising' followed by the closed language 'consisting' followed by a statement that broadens (up to 50 amino acids in length) from consisting of SEQ ID NO: 2,6,10, and 12 (SEQ ID NO:2,6,10, and 12 are each 12 amino acids in length). Section 2111.03 of the MPEP states that the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. A peptide consisting of SEQ ID NO:2,6,10,or 12 can only be 12 amino acids in length. However, claim 46 is drawn to peptides up to 50 amino acids in length. Further, dependent claim 62 states that the peptide is cyclic. A cyclic peptide of claim 62 would require an additional element as compared to the peptide

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consisting of SEQ ID NO:2,6,10, or 12 as recited in claim 46. It is noted that the sequences (SEQ ID NO:2,6,10, and 12) do not recite or give any indication that the peptides are cyclic (for example, via a disulfide bond between cysteine residues). As such, the scope of claim 46 and dependent claims 58 and 62 is unclear since the claims appear to be drawn to both open and closed language.

Applicant has amended claim 44. In the amendment applicant has used strikethrough to show deletion of the reference to SEQ ID NO:2. However, it is unclear if the reference to SEQ ID NO:4 is deleted as well. It is noted that 37 CFR 1.121 (c)2 states that

“The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.”

In the instant case, it cannot be easily perceived if the strikethrough used in claim 44 also includes the number 4. As such it is unclear if claim 44 is drawn to SEQ ID NOs: 4,6,8,10, and 12 or if the claim is drawn to SEQ ID NOs: 6,8,10, and 12

### *Response to Arguments*

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that claim 37 has been amended such that the peptide consists of SEQ ID NO:6 or 10.

Applicant's arguments filed 11/13/07 have been fully considered but they are not persuasive.

Claim 60 which depends from claim 37 recites that the peptide is a cyclic peptide. A cyclic peptide of claim 60 would require an additional element as compared to the peptide of claim 37. It is noted that the sequences (SEQ ID NO:6 and 10) do not recite or give any indication that the peptides are cyclic (for example, via a disulfide bond between cysteine residues). As such, the scope of claim 37 and dependent claims 53,56,60 is unclear since the claims appear to be drawn to both open and closed language.

For these reasons, the reasons above, and the reasons set forth previously the rejection is maintained.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 46,58** are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Cancer Letters 171 (2001) 153-164).

Zhang teach the peptide p160 of sequence VPWMEPAYQRFL (page 156 2<sup>nd</sup> column 1<sup>st</sup> line and Figure 1) which is identical to SEQ ID NO:2 of the instant invention. This peptide is less than 50 amino acids and is linear (compare claims 46,58 of the instant invention). Zhang

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further teach that the peptide t160 (VPWMEPAYQRFL) is chemically synthesized and used in assays (page 157 section 3.3 1<sup>st</sup> sentence). Zhang specifically teach the t160 peptide at different peptide concentrations (figure 2) so the peptide is necessarily present in a diluent.

Although unclear (see 112 2<sup>nd</sup> above) the claims have been interpreted as reading on open language (comprising). However, it is noted that art cited reads on consisting language as well.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 44,70** are rejected under 35 U.S.C. 103(a) as being unpatentable over Puzas (US 2005/0112168) and Balian (WO 03/072593).

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Puzas teach a peptide identified as SEQ ID NO:24 (page 60) of sequence SAHGTSTGVPWP which is identical to SEQ ID NO:8 of the instant invention. Puzas teach the peptide in compositions (claim 8, for example). Puzas specifically teach the peptide for use for methods of regulating bone formation (section 0295).

Puzas does not expressly teach the peptide in combination with other peptides of the instant invention.

Balian teach a peptide identified as SEQ ID NO:16 (page 5/9 of the figures) of sequence LLADTTHHRPWT which is identical to SEQ ID NO:4 of the instant invention. Balian teach compositions including the peptide (SEQ ID NO:16) (claim 1,8). Balian teach the peptide is used for enhancing bone repair (claim 12).

Both Puzas (section 0295) and Balian (claim 12) teach methods for enhancing bone formation/repair using compositions containing particular peptides. Since the peptides are individually taught in the prior art for a similar purpose one would be motivated to combine the peptides resulting in a composition with the peptides SAHGTSTGVPWP and LLADTTHHRPWT (compare claims 44,70 of the instant invention). The idea of combining them flows logically from their having been individually taught in the prior art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

It has been recently held that “Neither §103's enactment nor *Graham's* analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art.” KSR v. Teleflex, 550 U.S. \_\_\_, 82 USPQ2d 1385, 1389 (2007). The KSR court stated that “a combination of familiar elements according to

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known methods is likely to be obvious when it does no more than yield predictable results." KSR at 1389.

Furthermore, The KSR court concluded that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in *KSR*

When there is motivation

"to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, \_\_\_, 82 USPQ2d 1385, 1397 (2007).

In the instant case, all the claimed elements (the peptide SAHGTSTGVPWP as taught by Puzas; the peptide LLADTTHHRPWT as taught by Balian) were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Although unclear (see 112 2<sup>nd</sup> above) claim 44 has been interpreted as SEQ ID NO:4 being a part of the claims. If the strikethrough were intended to go thru the number 4 it would have also extended thru the comma after the 4 which it does not. Further, on page 11 (first full paragraph) of the reply dated 11/13/07 applicant states that claim 44 has been amended so as to

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not recite combinations of SEQ ID NO:2 and 12. It appears that applicants intent was to merely delete SEQ ID NO:2.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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